

REMARKS

In this Amendment, claims 1-12 are cancelled, and replaced with new claims 17-34. After entry of this Amendment, claims 13-34 will be pending in the application, of which claims 13-16 are currently withdrawn.

I. New Claims 17-34

The new claims recite a method for treating a mammal having a proliferative disease characterized by skin inflammation.

The invention as currently claimed is supported throughout the specification, and by original claims 10 and 11.

For example, pages 1-8 of the specification describe the invention as relating to the treatment of various such proliferative diseases such as psoriasis, lichen, atopic dermatitis, granuloma annulare, and mycosis fungoides (see page 8, lines 28-31, in particular). Page 10 further describes the invention as inhibiting the production of the inflammatory cytokines IL-6 and IL-8 in such treatment (also see Example 2, Figure 2, and original claims 10 and 11). Pages 1-4 describe the inflammatory pathology of psoriasis in detail, which is a “chronic inflammatory dermatitis” (see page 1, lines 23-25).

The invention as recited in independent **claim 17** comprises topically administering to a mammal an effective amount of a pharmaceutical composition comprising an aqueous *Curcuma* extract.

This aspect of independent claim 17 is supported by the original claims, such as original claims 1, 8, and 13. Additional support can be found in the specification at, for example, the paragraph bridging pages 8 and 9, page 11, and page 13.

Independent **claim 17** further recites “subjecting said mammal to ultraviolet radiation,” which is supported by original claim 2, and pages 15-16 describing Figures 1-3. Also see, page 21.

Independent **claim 28** recites topically administering to a mammal an effective amount of a pharmaceutical composition comprising a hydro alcoholic *Curcuma* extract.

This aspect is supported by the specification at page 10, lines 13-17, and page 13, lines 4-20.

Independent **claim 28** further recites “irradiating said mammal with a lamp that radiates visible light having a spectrum of 400-550 nanometers.”

This aspect is supported by the specification at page 9, lines 21-25, and page 27, lines 32-34.

Independent **claim 28** further recites “subjecting said mammal to ultraviolet radiation,” which is supported by original claim 2, and page 16 describing Figures 2 and 3. Also see, page 21.

The dependent claims are supported as follows.

Claims 18 and 29 are supported by original claim 12 and page 8, lines 25-31.

Claims 19 and 22 are supported by the specification at page 14, lines 10-31.

Claims 20 and 30 are supported by the specification at page 14, lines 10-12, and page 15, lines 15-21.

Claim 21 is supported by the specification at page 19-20.

Claim 23 is supported by the specification at page 5, line 28, and page 14, lines 10-18.

Claims 24 and 32 are supported by the specification at page 8, line 28, for example.

Claims 25 and 33 are supported by the specification at page 9, lines 8-13 and lines 21-25, for example.

Claim 26 is supported by original claim 11.

Claims 27 and 34 are supported by original claim 9. Also see page 11 of the specification.

Claim 31 is supported by page 25.

No new matter has been introduced. Entry of this Amendment is requested.

II. Summary of Claimed Invention

The present invention is a method for treating a mammal having a proliferative disease characterized by skin inflammation by taking advantage of the photosensitizing properties of *Curcuma* extracts, which surprisingly, do not have the mutagenic effects observed with conventional photosensitizing compounds, such as psoralens.

These features are described in the specification. The paragraph bridging pages 4 and 5 and page 7, lines 20-25, describe the limitations in psoralen treatment, and the paragraph bridging pages 9 and 10 states:

Further, the most important advantage is that in studies on eukaryote cells (human keratinocytes) the activated curcumin (present in apolar extracts) was found in the cytoplasm, therefore the nuclei is free from curcumin and the extract does not interact with nuclear DNA and mutagenic effects shown by other drugs, for instance psoralens, do not appear.

The presently claimed invention is novel and non-obvious as further established below.

II. Response to Claim Rejections Under 35 U.S.C. §102(b)

(1) At page 2 of the Office Action, claims 1 and 5-12 are rejected under 35 USC §102(b), as being anticipated by Deshpande et al. (Cancer Letters, 1997) or by Kuttan et al. (Cancer Letters, 1986).

Specifically, the Examiner states that Deshpande et al. disclose treating forestomach tumors in mice by administering *Curcuma* extracts.

With respect to Kuttan et al., the Examiner states that Kuttan et al. disclose treating lymphoma tumors in mice by administering a *Curcuma longa* extract.

The present claims are drawn to a method for treating a mammal “having a proliferative disease characterized by skin inflammation,” and require in addition to topically administering a pharmaceutical composition comprising *Curcuma* extract, subjecting the mammal to ultraviolet radiation.

In contrast, Deshpande teaches oral administration of *Curcuma* extracts, and Kuttan teaches intraperitoneal administration of *Curcuma* extracts, and for the treatment of forestomach and lymphoma tumors, respectively.

In addition, independent claims 17 and 28 recite “subjecting said mammal to ultraviolet radiation.” Original claim 2, which recited “subjecting said mammal to radiation,” was not rejected over Deshpande or Kuttan.

Neither Deshpande nor Kuttan teach the invention as defined by the present claims, and thus withdrawal of this rejection is requested.

(2) At page 3 of the Office Action, claims 1, 5 and 9-12 are rejected under 35 USC §102(b) as being anticipated by Shah (US Patent No. 5,693,327).

Specifically, the Examiner contends that Shah discloses treating various conditions associated with a proliferative disease, including psoriasis, by administering a composition that contains a *Curcuma longa* and/or *Curcuma aromatica* aqueous extract.

Independent claims 17 and 28 recite “subjecting said mammal to ultraviolet radiation.” Original claim 2, which recited “subjecting said mammal to radiation,” was not rejected over Shah.

Independent claim 28 further recites “irradiating said mammal with a lamp that radiates visible light having a spectrum of 400-550 nanometers,” as was the subject of original claim 4, which was also not rejected over Shah.

Since the present claims include limitations present in the original claims, which were not rejected over Shah, withdrawal of this rejection is requested.

(3) At page 4 of the Office Action, claims 1 and 5-12 are rejected under 35 USC §102(b) as being anticipated by Almagro et al. (ES 2 103 689).

Specifically, the Examiner contends that Almagro et al. disclose treating a condition associated with a proliferative disease in a mammal by administering one or more (aqueous and/or ethanolic) extracts of *Curcuma longa* rhizomes.

Since the present claims include limitations present in original claims 2 and 4, which were not rejected over Almagro et al., withdrawal of this rejection is requested.

III. Response to Claim Rejections Under 35 U.S.C. §103(a)

(1) At page 5-6 of the Office Action, claims 1-12 are rejected under 35 U.S.C. §103(a) as being obvious over Deshpande et al., (Cancer Letters 1997), Kuttan et al. (Cancer Letters 1986), and Paek et al. (Arch. Pharm. Res. 1996), in view of Otsuka et al (JP 11-151309).

Specifically, the Examiner acknowledges that neither Deshpande nor Kuttan teach treating cancers such as leukemia.

However, the Examiner states that Paek et al. teach *Curcuma longa* extract for treating human leukemia cells *in vitro*, so as to induce leukemia cell death.

The Examiner acknowledges that none of Deshpande, Kuttan, and Paek teach the further use of radiation for cancer treatment.

However, the Examiner states that Otsuka et al. teach the use of a light radiation device to selectively suppress the propagation of cancer cells in a subject, whereby the device selectively radiates visible light, preferably in the range of 430-530 nanometers.

The Examiner reasons that it would have been *prima facie* obvious to administer an aqueous and/or ethanolic *Curcuma longa* extract to treat cancer and/or leukemia, and to further treat such subjects with light radiation.

The present claims are drawn to treatment of a proliferative disease characterized by skin inflammation, which is not the subject of any of Deshpande, Kuttan, Paek and/or Otsuka.

Accordingly, Deshpande, Kuttan, Paek and Otsuka, each alone or in combination, do not render the present invention obvious.

Withdrawal of this rejection is therefore requested.

(2) At pages 6-8 of the Office Action, claims 1-12 are rejected under 35 U.S.C. §103(a) as being obvious over Shah (US Patent 5,693,327) and Bernd et al. (J. Invest. Dermatol. 1997), in view of Wilkens (DE 4440112).

The Examiner states that Shah teaches treating various conditions associated with a proliferative disease, including psoriasis, by administering a composition that contains a *Curcuma longa* and/or *Curcuma aromatica* aqueous extract.

The Examiner further states that Bernd et al. teach that an aqueous-alcoholic *Curcuma longa* extract is effective against proliferative diseases such as those involving increased IL-6 and IL-8 cytokine production, including psoriasis.

The Examiner acknowledges that neither Shah nor Bernd et al. teach the further use of radiation for treating proliferative conditions such as psoriasis.

However, the Examiner contends that Wilkens teaches the use of light radiation within the visible range of 400-800 nanometers for the treatment of psoriasis.

The Examiner reasons that it would have been prima facie obvious to administer an aqueous and/or ethanolic *Curcuma longa* rhizome extract to treat a proliferative disease such as psoriasis, and to further treat such subjects with light radiation.

The present claims recite “subjecting said mammal to ultraviolet radiation.”

None of Shah, Bernd or Wilkens suggest using UV light to treat psoriasis, and as such, alone or in combination, the cited does not render the present invention obvious.

Further, the cited art does not teach the important feature of the invention, the fact that the claimed treatment does not induce mutagenic effects, as can be problematic with conventional photosensitizing compounds such as psoralens.

Withdrawal of this rejection is requested.

(3) At pages 8 and 9 of the Office Action, claims 1-12 are rejected under 35 U.S.C. §103(a) as being unpatentable over Quintanilla Almagro et al. (ES 2 103 689).

Specifically, the Examiner contends that Almagro teaches treating a condition associated with a proliferative disease, such as those related to skin aging, by administering extracts of *Curcuma longa* rhizomes. The Examiner states that Almagro teaches that *Curcuma longa* extracts *protect cells from* UV radiation *in vitro*.

The Examiner reasons that it would have been *prima facie* obvious to administer one or more *Curcuma* extracts to a subject, who has been, or who would subsequently be, exposed to UV radiation, based upon the UV protective effect of *Curcuma* extracts shown by Almagro.

The present claims are drawn to a method of treating a mammal having a proliferative disease characterized by skin inflammation, and which comprises administering a *Curcuma* extract and subjecting the mammal to ultraviolet radiation.

In contrast, Almagro does not teach treatment of *any condition*.

Further, Almagro does not suggest that further treatment with UV or visible light would enhance the therapeutic effect of a *Curcuma* extract in the treatment of a proliferative disease characterized by skin inflammation.

Accordingly, Almagro does not teach or suggest the claimed invention, and thus withdrawal of this rejection is requested.

IV. Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.


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